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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,121	08/30/2001	Zvi Sidelman	01/22453	6939

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,121	SIDELMAN, ZVI	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-283 is/are pending in the application.

4a) Of the above claim(s) none is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-283 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-8, drawn to a method of treating an autoimmune disease comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 2. Claims 9-12, drawn to a method of preventing viral infection comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 3. Claims 13-25, drawn to a method of inducing hematopoiesis comprising administering to a subject a polypeptide comprising N- terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 4. Claims 25-32, drawn to a method of inducing megakaryocytopoiesis administering to a subject a polypeptide comprising N- terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 5. Claims 33-40, drawn to a method of inducing leukocytopoiesis comprising administering to a subject a polypeptide comprising N- terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 6. Claims 41-52, drawn to a method of inducing plasma cell proliferation comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 7. Claims 53-56, drawn to a method of treating thrombocytopenia comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 8. Claims 57-64, drawn to a method of treating pancytopenia comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 9. Claims 65-68, drawn to a method of treating thyperlipidemia comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 10. Claims 69-72, drawn to a method of treating cholesteremia comprising administering to a s; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 11. Claims 73-76, drawn to a method of treating glucosuria comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 12. Claims 77-80, drawn to a method of treating diabetes comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 13. Claims 81-88, drawn to a method of treating AID comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein, are classified in class 514, subclass 2.

Group 14. Claims 89-96, drawn to a method of treating conditions associates with myeloablative doses of chemoradiotherapy comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 15. Claims 97-100, drawn to a method ofaugmenting the effect of thrombopoietin comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment

has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 16. Claims 101-104, drawn to a method of enhancing peripheral stem cell Mobilization comprising administering to a subject a polypeptide comprising N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

Group 17. Claims 105-259, drawn to a pharmaceutical composition comprising a peptide fragment derived from N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, and a pharmaceutically acceptable carrier, are classified in class 530, subclass 300, class 514, subclass 2, and class 424, subclass 278.1.

Group 18. Claims 260-283, drawn to a method of enhancing colonization of donated blood stem cells in a myeloablated recipient enhancing peripheral stem cell comprising administering to a subject a peptide fragment derived from N-terminus portion of oS1 casein; the said peptide fragment has one of sequences of SEQ ID NOs:1-25, are classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-16 and 18 are directed to different and/or distinct methods. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper among the methods of Inventions 1-16 and 18 since they constitute distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome. Each method therefore is patentably distinct.

Invention 17 is related to Inventions 1-16 and 18 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition comprising N-terminus portion of oS1 casein can be immobilized on a

protein chip surface for investigating a signaling pathway or portion-protein interaction, for example.

Additional Election

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disclosed composition to which claims are restricted; and (2) to list all claims readable thereon as directed to the elected invention.

If any Group from Groups 1-18 is elected, applicant is required to elect one peptide sequence with identified SEQ ID NO: from the claim(s) where recites "SEQ ID NOs:___" because these peptide sequences are structurally (in both composition and sequence) distinct/different from one another; and thus, they patentably distinct from one another.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.
The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on

Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

SWL

Samuel W. Liu, Ph.D.
June 21, 2004